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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,795	11/26/2003	Claudiu Supuran	MST-2393 U.S.	9070

24988 7590 10/12/2006

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,795	SUPURAN ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 6, 22-25, 27, 52 and 59-62, as specifically drawn to a method of treating a mammal for a pre-cancerous or cancerous disease characterized by overexpression of a MN/CA IX protein, comprising administering to said mammal a therapeutically effective amount of a composition comprising a compound, wherein the compound is an inorganic molecule, classified in class 424, subclass 1.61.

II. Claims 2-4, 7-17, 23-25, 53 and 59-62, as specifically drawn to a method of treating a mammal for a pre-cancerous or cancerous disease characterized by overexpression of a MN/CA IX protein, comprising administering to said mammal a therapeutically effective amount of a composition comprising a compound, wherein the compound is an aromatic sulfonamide, classified in class 514, subclass 601.

III. Claims 2-4, 7-15, 18-21, 23-25, 53 and 59-62 as specifically drawn to a method of treating a mammal for a pre-cancerous or cancerous disease characterized by overexpression of a MN/CA IX protein, comprising administering to said mammal a therapeutically effective amount of a composition comprising a compound, wherein the compound is an heterocyclic aromatic sulfonamide, classified in class 514, subclass 279, 363 and 367.

IV. Claims 2-4, 23-25, 28-51, 53 and 59-62, as specifically drawn to a method of treating a mammal for a precancerous or cancerous disease, wherein said disease is characterized by overexpression of MN/CA IX protein, comprising administering to said human a therapeutically effective amount of a composition comprising a membrane-impermeant compound, wherein said membrane impermeant compound is a pyridinium derivative of an aromatic sulfonamide or heterocyclic sulfonamide, classified in class 514, subclass 277.

V. Claims 54-58, as specifically drawn to a pyridinium derivative of a heterocyclic sulfonamide, classified in class 546, subclass 268.7.

VI. Claims 63-66, as specifically drawn to a method of treating a mammal for a precancerous or cancerous disease characterized by overexpression of MN/CA IX protein, comprising administering to said mammal a therapeutically effective amount of a vector conjugated to a potent CA IX specific inhibitor, classified in class 514, subclass 44.

VII. Claims 67-69, as specifically drawn to a method of imaging tumors and/or metastases that express CA IX in a patient comprising administering a CA IX-specific inhibitor linked to a imaging agent, classified in class 424, subclass 9.1.

Linking Claims:

Claims 1, 5, 22, 26 and 52 link(s) the inventions of Groups II-IV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1, 5, 22, 26 and 52. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Note: If Applicants were to elect the invention of Group III, Applicant is required under 35 U.S.C. 121 to further elect a single disclosed invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Group III contains claims, 15 and 21, directed to the following patentably distinct inventions, NOT species:

i) Heterocyclic sulfonamide compounds having the structures of 13, 14, 15, classified in class 514, subclass 363;

ii) Heterocyclic sulfonamide compounds having the structure of 21, classified in class 514, subclass 367; or

iii) Heterocyclic sulfonamide compound having the structure of 22, classified in class 514, subclass 279.

Each of the specifically claimed heterocyclic sulfonamide compounds lack unity of invention because heterocyclic sulfonamide compounds have no substantial structural similarities although they have a common utility, i.e. inhibitors of MN/CA IX. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-V are directed to related methods of treating cancerous and/or precancerous conditions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed performs the method of treating using structurally divergent material. As such, the inventions of Groups I-VI are patentably distinct.

Furthermore, the distinct products require separate and distinct searches of the patent and non-patent literature. The inventions of Groups I-VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VI

The inventions of Groups I-VI and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method for treating a precancerous and/or cancerous disease in a mammal (Groups I-VI) and a method of diagnosing and/or imaging a tumor in a patient (Group VII) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection and treatment differ significantly for each of the materials. For these reasons the inventions of Groups I-VI and Group VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-VI and Group VII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VI and Group VII together.

The inventions of Group V and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process such as the in vivo imaging of a tumor.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is

not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species:

Claims 15 and 16 of Group II are generic to a plurality of disclosed patentably distinct species comprising the following aromatic sulfonamide structures: 1-12, 16-19, 23-24.

The above species represent separate and distinct aromatic sulfonamide structures which differ in chemical structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Claim 26 of Group IV is generic to a plurality of disclosed patentably distinct species comprising the following pyridinium derivatives:

i) a pyridinium derivative of an aromatic sulfonamide as described in claim 36; and

ii) a pyridinium derivative of a heterocyclic sulfonamide as described in claim 45.

The above species represent separate and distinct pyridinium derivatives which differ in chemical structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Claim 60 of Groups I-IV is generic to a plurality of disclosed patentably distinct species comprising the following compounds:

i) conventional anticancer drugs;

ii) chemotherapeutic agents;

iii) different inhibitors of cancer-related pathways;

iv) bioreductive drugs;

v) CA IX-specific antibodies; and

vi) CA IX specific antibody fragments.

The above species represent separate and distinct compounds which differ in chemical structure, site of action and mode of action such that one species could not be interchanged with the

other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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